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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	CR-18-00258-EJD JOINT STATUS MEMORANDUM

The parties in the above-captioned matter hereby file this joint status memorandum in advance of the hearing set for November 4, 2019. Statements from the government (Section I) and from the defense (Section II) are set forth below.

I. Government's Statement

A. The October 2, 2019 Hearing and Subsequent Developments

Defendants have filed a motion to compel production of documents from FDA and CMS. (Dkt. No. 67). The problem with Defendants' motion is that it seeks an order from the Court compelling the *prosecution* to produce the requested documents. Those documents, however, are in the possession,

custody, and control of FDA and CMS, and the prosecution does not have access to those materials. The defense contests that fact, but the record in this case proves the prosecution's lack of access, and there is no dispute that the prosecution's discovery obligations do not extend to documents to which the prosecution lacks access.[1]

In its briefing in response to Defendants' motion, and at subsequent hearings, the government has made clear that it has no objection to Defendants obtaining the documents they seek from the agencies. Indeed, the prosecution has done everything in its power to retrieve the requested materials on Defendants' behalf. Shortly after Defendants filed their motion, the government sent written requests to FDA and CMS asking for all of the document categories listed in Defendants' filing. The government then worked with the agencies to find solutions to challenges that would slow down or limit their production. On July 9, 2019, FDA sent a letter to all counsel in this case confirming its agreement to produce "all documents responsive to all six categories requested by the parties." (Dkt. No. 89-2). On July 12, 2019, CMS sent a letter memorializing its agreement to produce documents in its possession responsive to the government's requests. (Dkt. No. 89-3). From that date forward, the agencies have never withdrawn their agreements to produce responsive documents and, based on the prosecution's understanding of the facts, the agencies have worked diligently to follow through on those agreements. The defense complains that the agencies have not completed their productions, but

Leading up to the last hearing on October 2, 2019, the agencies made several productions of responsive documents consistent with their agreements to produce, and updated the parties regarding the status of their efforts. The defense raised several complaints regarding the approaches the agencies had taken to collect and produce documents. Following the hearing on October 2, 2019, the Court issued an Order requiring the parties to meet and confer with FDA and CMS regarding the issues Defendants had

[1] In a footnote below, the defense asks the Court to accept that the prosecution's agreement to produce discoverable materials held by FDA-CI Special Agent Scavdis means that the prosecution must have full access to the files of all FDA employees. This simply does not follow. The prosecution has never disputed that Special Agent Scavdis is a member of the investigative team, and that the prosecution is therefore able to ensure that any discoverable documents in his possession are produced. Indeed, the prosecution has been producing such documents and will continue to do so as required by its discovery obligations. But Scavdis's work as a special agent in this case does not prove the government's access to all of FDA's millions of regulatory records any more than the presence of U.S. Postal Inspection Service agents on the team confers access to every piece of paper maintained by the Postal Service.

raised regarding the agencies' document productions. (Dkt. No. 134). The Order also required the agencies to complete their document productions by October 25, 2019. (*Id.*).

On October 23, 2019, the parties participated in a telephonic meet-and-confer discussion including counsel representing FDA and CMS. That two-and-a-half-hour call—along with ongoing email correspondence between the parties—has afforded defense counsel opportunities to raise their specific questions with the agencies and gain useful information regarding the agencies' approach to document collection, review and production. The government offers the following update based on information learned from the agencies during those discussions.

B. The Agencies' Good-Faith Efforts to Address Defendants' Remaining Objections and the Current Status of Their Productions

1. CMS

The government understands that CMS has completed the first phase of its production and is currently working as quickly as possible to capture and produce any remaining documents from the time period recently expanded based on Defendants' requests.

In advance of the October 2, 2019 hearing, Defendants raised complaints regarding CMS's use of a date restriction (September 1, 2013 through December 31, 2016) in collecting and producing documents in response to the government's request. This objection understandably took CMS by surprise for several reasons. First, CMS had determined that its selected date range would capture the bulk of documents responsive to the six requests, and that its previous collection efforts would have captured any relevant documents from an earlier time period. Second, Balwani's counsel had proposed that very date range for CMS's document production in response to Balwani's subpoena in the SEC civil case. Third, CMS's July 12, 2019 letter had expressly indicated its intention to use that date range in collecting documents to respond to the government's request, and the Court had quoted that portion of CMS's letter in acknowledging the agency's agreement to produce responsive documents. In other words, CMS believed in good faith that its use of that date restriction was in compliance with the Court's order.

Following the October 2, 2019 hearing, CMS reviewed the Court's latest Order and the transcript from the hearing and came to understand that the Court wanted the agency to collect and produce

documents beyond its originally selected date range. In response, CMS immediately started that process, going back to its selected custodians and using search terms to collect documents going back to 2010 as requested by Defendants. Once that step was complete, CMS sent the collected documents to DOJ's Litigation Technology Service Center ("LTSC") so that LTSC could load those documents onto a database for CMS's review. That process is now complete and the documents are being prepared for review. Once CMS has access to the collected documents again on or about November 4, 2019, it will review the documents for responsiveness, privilege, and any other non-discoverable information, and select appropriate documents for production to the parties in this case. CMS estimates that this review will take approximately ten business days. LTSC will then process the document production—a final step that will take an estimated two weeks given LTSC's bandwidth. CMS will produce discoverable documents from this recently collected set as soon as possible. As discussed above, the timing of this production is driven primarily by factors outside CMS's control.

In connection with the expected additional production from CMS, it is important to note that the recent collection was relatively small, consisting of fewer than 900 documents after internal deduplication. CMS does not have the ability to deduplicate its upcoming production against the materials that it collected in response to the government's original request in 2017—materials that the government produced to the defense long ago. That means that this expected production may consist largely of documents that Defendants already have. CMS has indicated that it is willing to take on this potentially duplicative effort in order to accommodate the parties' requests and to avoid further dispute.

After reviewing CMS's recent productions, defense counsel identified a single CMS custodian who appeared not to be included in the agency's 2019 productions. Counsel for CMS explained to the defense that this custodian had only minimal involvement with Theranos early in the process, and that all of that custodians responsive documents had already been collected and provided to the prosecution in 2017. Following the October 23 call, CMS informed the parties that it had confirmed that the identified custodian's responsive documents had been collected and produced previously.

In response to additional questions from defense counsel, CMS also provided information regarding its data preservation practices with respect to current and former employees, confirming that those practices would have preserved relevant information in this case. CMS counsel also agreed to

confirm that non-electronic documents had been retrieved and produced, and subsequently confirmed for the parties that the majority of such documents would have been collected and produced to the prosecution in 2017. CMS is following up to locate and produce any additional responsive hardcopy files as soon as possible.

The prosecution is informed that the civil DOJ lawyer representing CMS plans to be present at the November 4, 2019 hearing, and that CMS in-house counsel will be standing by and willing to appear by phone should the Court wish to contact them for additional information.

2. FDA

FDA has completed the production of the documents it initially collected in response to the Court's July 19, 2019 Order. In addition, FDA has been responsive to Defendants' recently raised concerns, expanding its collection to include additional custodians identified by the defense. The review and production of materials from those custodians will be completed as soon as possible, but it will take approximately another month to load them onto the agency's review platform.

As explained in FDA's previous updates to the parties, the agency encountered technical issues in processing some of its materials that delayed production of a small subset of documents. Notwithstanding Defendants' speculation that these problems might be evidence of deleted files, FDA has said no such thing to the prosecution. FDA has been working on these technical issues and has resolved them to the extent possible. On the October 23 call, the agency provided an update regarding its continuing efforts to address technical issues as to one or two discrete categories of collected documents. Many documents previously subject to technical issues were produced on October 25.

The FDA's October 25 production also included at least one Spanish-language document that took the agency longer to review. Additionally, although the agency previously held off on reviewing documents from its Office of Chief Counsel, it has since reviewed those materials, and responsive, non-privileged documents were transmitted to the parties as part of the October 25 production.

After the October 2 hearing, the prosecution and the agencies sent multiple requests to defense counsel asking for specific information as to which custodians Defendants believed were improperly left out of the FDA's recent production. Eventually, on October 11, 2019, Defendants identified a handful of FDA document custodians who appeared not to have been included in the agency's 2019 collection

and productions. The FDA has reviewed that list of custodians and determined, based on their roles with respect to Theranos and overlap with other selected custodians, that it was reasonable not to include them in the initial round of collection. Although the agency stands by its original approach to document collection, it has informed the parties that it is expanding its collection efforts to include each of the custodians recently identified by the defense. To the extent those custodians are current FDA employees, the agency has already contacted them to initiate document collection. As to any former custodians on the list, FDA's information management staff estimate that it will take approximately four weeks to retrieve their documents.

Based on its knowledge of these custodians' roles, FDA anticipates that the number of unique and responsive documents collected from recently identified custodians will be relatively small. Like CMS, FDA cannot deduplicate its production against what it provided to the government in 2017, so it is likely that the defense already has many of the outstanding documents. FDA will, however, deduplicate the documents it is collecting now against its 2019 productions in order to accelerate its production. As these documents are compiled, FDA will load, review, and produce any responsive and discoverable materials as quickly as possible.

On the October 23 call, FDA provided responses to questions from the Defendants regarding document preservation for employees who have left the agency, the collection of non-electronic documents, and the time periods covered by FDA's collection efforts. FDA's answers on these topics gave no indication that relevant evidence had been lost or ignored.

Defendants have taken issue with redactions in FDA's production, alleging that the agency improperly withheld information necessary to understand the context of responsive communications. The prosecution and the agencies have requested that the defense provide examples of the purported overbroad redactions so that agency counsel can review them. Prior to the October 23, 2019 call, defense counsel sent a small number of example documents. FDA counsel has reviewed those specific documents and examined the unredacted versions to confirm for the parties that the redacted information is unambiguously nonresponsive, i.e., that it has nothing to do with Theranos. FDA has recently confirmed for the parties that it waived its deliberative process privilege as to Theranos, and did not redact or withhold Theranos-related documents on that basis. According to FDA counsel, its practice of

redacting such nonresponsive information sped up its production by allowing it to bypass the more granular review for privilege and third-party confidential commercial information. Contrary to Defendants' claims, the agency did not state that it used this method to avoid a careful *responsiveness* review. Nor did the agencies withhold information based on their views concerning what issues are relevant in this case. To date, the defense has not identified any documents where responsive information—or indeed any information about Theranos itself—was redacted. Regarding FDA's withholding of duplicate documents attached to emails in its production, the agency reports that it is currently evaluating its position on the issue after receiving from the defense a list of produced documents affected by this issue.

Finally, Defendants have objected to the absence of certain search terms in FDA's document collection protocols. The government agrees with the agencies that these complaints are unfounded. For example, Defendants contend that the terms "LDT" (an abbreviation for "laboratory developed test") and "waiver" should have been included as independent search terms in FDA's collection. In other words, Defendants' position is that the Court's Order entitles them to FDA documents that discuss the concepts of LDTs and waivers even if those discussions are not in the context of Theranos specifically and make no mention of the company. Defendants' relevance arguments aside, those documents simply are not covered by any of the six categories selected in Defendants' motion, the government's document requests, and the Court's Order. In fact, Balwani tacitly acknowledged as much in the SEC civil case; his subpoena to FDA included several document requests beyond the six at issue here, and that list of additional requests included at least one explicitly targeting information about LDTs. FDA should not be blamed for Defendants' failure to include that topic in the list of categories they selected in the criminal case.

The prosecution is informed that the civil DOJ lawyer representing FDA plans to be present at the November 4, 2019 hearing, and that FDA in-house counsel will be standing by and willing to appear by phone should the Court wish to contact them for additional information.

II. Defendants' Statement on FDA/CMS Productions

The Court has now twice ordered the FDA and CMS to complete their productions of all documents responsive to the defense's requests by a date certain. Most recently, on October 2, 2019,

after the agencies failed to meet the initial deadline set by the Court, the Court again ordered that production be completed "no later than October 25, 2019." ECF No. 134. October 25 has come and gone, and the agencies' productions are far from complete. In addition to the continued delays, the agencies are (1) unable to confirm that all responsive documents have been preserved, searched for, collected, and will be produced, (2) incapable of providing credible estimates of when their productions will be complete, and (3) in the case of FDA, are producing thousands of redacted documents and blank pages labeled "intentionally withheld." Notwithstanding the Court's clear directives on the matter, significant questions and uncertainties remain regarding when or if the defense will receive many of the important agency documents it has been seeking.

The defense filed its motion to compel production of these materials on April 15, 2019. ECF No. 67. The Court held a hearing on the motion on June 28, 2019, after which the Court entered an Interim Order that the "FDA and CMS shall provide the parties with specific information regarding the documents they agree to produce or object to producing." ECF No. 84. On July 19, 2019, following a second hearing on the defense's motion, the Court ordered the FDA and CMS to "search for and produce to the Prosecution all documents responsive to the six categories of documents" in Defendants' motion. ECF No. 111. The Court further ordered the FDA and CMS to complete their productions no later than October 2, 2019. *Id.* The agencies failed to do so. The parties appeared before the Court for a third hearing on the same motion, after which the Court again ordered the FDA and CMS to complete their productions, this time by October 25. ECF No. 134. At the hearing, the prosecution represented to the Court and the parties that the agencies were "on track to complete their productions of responsive documents either today or in the very near future."[2] That has not happened.

Pursuant to the Court's October 2, 2019 Order, the defense met and conferred with the FDA, CMS, and the prosecution over the last several weeks regarding Defendants' concerns with the agencies' productions. A civil Assistant United States Attorney from the same office as the prosecution, and who has been intimately involved in the agencies' production efforts, participated extensively in these conversations. The defense sought a response to the same question it has been asking for months: would

[2] Transcript of Proceedings Before the Honorable Edward J. Davila (October 2, 2019), at 4:12-14.

the FDA and CMS produce *all* documents responsive to the motion, and when? The answers from both the prosecution and the agencies revealed why they have been so reluctant to provide a direct response to a simple question: a troubling lack of diligence in ensuring that all responsive documents have been preserved, searched for, collected, and will ultimately be timely produced.

During the October 23, 2019 meet and confer between the prosecution, the civil AUSA, agency counsel, and the defense, the defense learned for the first time of a number of glaring deficiencies in the agencies' preservation and collection efforts. The agencies also could not provide clear estimates of the timing of further productions, leaving the defense once again in the dark about if and when the agencies' productions will be completed. The prosecution's speculation that the defense *probably* already has the outstanding documents is not correct; actual analysis of the data shows that over 95% of the documents produced by the agencies since the Court Order are new, not duplicative of prior DOJ productions.

A. CMS's Deficiencies

1. CMS has not made inquiries sufficient to assure the defense that all relevant documents and data for the full time period had been preserved.

2. CMS could not confirm that it had collected and produced all responsive non-email, hard-copy documents.

3. CMS could not provide a firm date by which the defense would receive documents from the 2010-2013 time period.[3] The status of any additional non-email or hard-copy document production from CMS is even hazier, as CMS would have only started collecting such documents days ago, at best.

B. The FDA's Deficiencies

1. The FDA could not confirm that it had preserved, collected, and produced all hard-copy documents for former employees, including employees who left the FDA *after* the prosecution issued a litigation hold in June 2017. This latter group of employees includes the primary FDA official with whom Theranos interacted.

[3] The government's statement claims that CMS was surprised by Defendants' objections to CMS's date restriction of September 1, 2013 through December 31, 2016. But Defendants' motion to compel—filed on April 15, 2019—specifically noted that "a CMS representative visited Theranos and toured its facilities in 2012" and that the "CDPH conducted an initial survey of Theranos in January 2012." ECF No. 67 at 4.

2. With respect to current employees, the defense learned that the FDA has instructed individual employees to manually search for responsive documents, including email, rather than perform a forensic collection, search, and review. The FDA's approach is unreliable and inconsistent with standard document collection practices. *See Nat'l Day Laborer Organizing Network v. USCIS*, Case No. 10-cv-3488 (S.D.N.Y. Jul. 13, 2012) (finding that "most custodians cannot be 'trusted' to run effective searches" and a "court cannot simply trust the defendant agencies' unsupported assertions that their lay custodians have designed and conducted a reasonable search").

3. The FDA could not provide an estimate as to when documents from additional, missing custodians would be produced, noting only that it would take at least *four weeks* just to locate and process the documents.

4. The FDA has taken other steps at a technical level that have deprived the defense of highly relevant—and exculpatory—evidence.[4] It appears that the FDA's approach to compliance with the Court's order is to look for ways to produce the narrowest possible set of documents. This includes not using "Theranos" as a standalone search term. The FDA also excluded key search terms necessary to fully comply with the Court's Order. For example, the FDA failed to include "Laboratory Developed Test" or "LDT" as search terms. They did not even search for "Theranos and LDT," among other crucial combinations. This is astonishing given how central the FDA's policies around the regulation of LDTs is to this case. Notwithstanding the prosecution's advocacy on behalf the agencies that these terms need not be searched, the agencies could not possibly produce all documents responsive to the Court's Order, especially categories 2 and 4, without these searches. The failure to deploy such central search terms likely explains the dearth of FDA documents created in 2014, Exhibit B (FDA Histogram), when the agency was heavily involved with making decisions about how and whether to regulate LDTs.

A. The FDA has either "intentionally withheld" or redacted at least 45% of its total production since the Court Order. Exhibit C (Pie Chart). Specifically, more than 4,586 documents that the FDA has produced pursuant to the Court's Order are blank pages marked as "Intentionally Withheld," including attachments to emails that are clearly responsive to the Court's Order. *See, e.g.*,

[4] Many of these deficiencies are set forth in an October 30, 2019 letter from FDA counsel. Exhibit A.

Exhibit D. The FDA claims that these documents are "duplicates" but they are not—e.g., the same document attached to three different emails with different recipients needs to be produced three times for each of the emails to have evidentiary use and significance. The FDA's approach has limited the evidentiary use of the documents and provided the defense with no ability to accurately locate these documents or establish as an evidentiary matter which witnesses had possession and knowledge of copies of the documents. Fundamentally, the FDA's stated position is not a proper basis to withhold highly relevant evidence.

B. Many of the documents that have been produced are also unintelligible due to the FDA's improper redactions for issues such as "non-responsiveness," "law enforcement," or "deliberative process." Exhibit E. These redactions are contrary to the prosecutions' and agencies' prior representations that the "FDA is not withholding responsive documents based on a determination of relevance" or "withholding documents … on the basis of deliberative process privilege." Dkt. 89-2 (FDA July 9, 2019 Letter); Dkt. 89 (July 15, 2019 Joint Status Memo). The FDA has stated that the documents it withheld under claims of deliberative process are unrelated to Theranos, but it is clear from the productions that the agency takes an extremely narrow view of that concept such that it is withholding, for example, key policy discussions that directly implicate regulation of Theranos's lab testing. The FDA even now admits that its "non-responsive" redactions are a catchall used to save time and avoid a careful review of the document for responsiveness. Exhibit A at 4.

C. The FDA was unable to explain the "technical issues" that led to hundreds of documents being withheld up until this point from the files of the primary FDA official with whom Theranos interacted. It appears that the term "technical issues" may be a euphemism for deleted files that the FDA is attempting to recover. *See* Exhibit A at 2 ("Approximately 1,114 partially-visible emails from custodian Alberto Gutierrez – there is no way to correct these email files. Accordingly, FDA is working to identify whether it has full versions of the emails from other custodians; to the extent it does not, it will produce the partially-visible emails.").

The information communicated by the agencies raises serious concerns about their efforts to comply with the Court's Orders to produce all documents responsive to the defense's requests, as well as the impact that the agencies' actions may have on the trial schedule. But it also throws into sharp

relief the pressing and continued need for a Rule 16 Order to hold the prosecution directly accountable for the agencies' productions.[5] The defense has consistently raised issues related to document preservation and collection. Yet it appears that the prosecution never bothered to inform the agencies that all documents responsive to the defense's requests should be preserved, collected, searched for, and produced. It is difficult to imagine that the prosecution would have done the same had it been subject to a Rule 16 Order. The defense has provided the government with examples of Brady material within recent productions that demonstrate far closer scrutiny of agency files is needed than has been demonstrated by FDA and CMS to date. The government must finally accept that it is not "off the hook for any Rule 16 obligation."[6] It is clear from the events to date that only the government would have the vested interest necessary to ensure compliance with the Court's Order to avoid the grave risk that Rule 16 and *Brady* material will go unpreserved and unproduced.

/ /

[5] The government again repeats its mantra that it lacks access to the agency documents. This is incorrect. Among other things, the record shows that the government's own agent had carte blanche access to FDA materials, even post-indictment. Notably, in the October 23, 2019 meet and confer call, the prosecution conceded that it currently has access to FDA files when it wants to control the production. In response to a defense request about email and other files of FDA-CI Special Agent Scavdis, the prosecution advised that it, and not FDA, would review and produce discoverable material, even where such documents are subject to the Order. The government makes an inapt analogy to the postal service in a footnote above, but the fact remains that the FDA agent had unfettered access to FDA files shattering the fiction that the government is a mere bystander here.

[6] Transcript of Proceedings Before the Honorable Edward J. Davila (October 2, 2019), at 17:8-9; *see also* Transcript of Proceedings Before the Honorable Edward J. Davila (July 16, 2019), at 40:6-17.

III. Proposed Pre-Trial Schedule

Consistent with the Court's order at the October 2, 2019 hearing, the parties jointly propose the pretrial schedule attached as Exhibit F be entered in this matter.

DATED: October 31, 2019

Respectfully submitted,

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Acting Under Authority Conferred
By 28 U.S.C. § 515

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DATED: October 31, 2019

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EXHIBIT A

U.S. FOOD & DRUG ADMINISTRATION

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October 30, 2019

Via Email

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Re: Document Request – *United States v. Elizabeth Holmes & Ramesh Balwani*, 18-CR-00258 EJD (N.D. Cal.)

Dear Messrs. Bostic, Downey, and Coopersmith:

I write to provide you an update on the status of the U.S. Food and Drug Administration's ("FDA") production of documents responsive to Defendants' motion to compel in the above-referenced case.

As set forth in detail in my September 23, 2019 letter to Mr. Bostic (Dkt. #121-2), FDA has taken great efforts to meet the Court-imposed deadlines to produce documents in this matter. Following the Court's July 19, 2019 Order ("Order"), FDA made productions on August 5, August 16, August 23, August 30, September 25, October 1, October 8, October 9,[1] and October 24, together totaling over 60,000 pages.[2] This production is in addition to the over 40,000 pages of documents that FDA produced to the U.S. Department of Justice ("DOJ") prior to the Court's Order that are in the possession of Defendants (*see* Dkt. #67, at 3).

FDA's September 23 letter explained that the agency anticipated that its October 1st production would include responsive, non-privileged documents from two buckets – (i) documents potentially responsive to the motion to compel categories that appeared to be unique, and (ii) documents potentially responsive to the motion to compel categories that, via a textual analysis, appeared to be duplicates of documents already in the

[1] FDA's October 8th and 9th productions consisted of documents identified to be responsive to Defendant Balwani's subpoena in the civil matter (18-cv-01603-EJD) that were nonetheless produced to the parties in this criminal matter pursuant to FDA's June 7, 2019 letter to the prosecution stating that, as FDA processed documents for the subpoena, it would provide those documents to the parties in this criminal matter (*see* Dkt. #79-4, at 2).

[2] This page count does not include pages that were produced with slipsheets stating "intentionally withheld" or "technical issue."

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possession of the parties, or duplicates of each other. FDA produced the responsive, non-duplicative, non-privileged documents from both buckets.

FDA's September 23 letter also explained that certain other documents would not be included in its October 1st production – (a) documents from FDA's Office of the Chief Counsel, (b) documents identified as containing foreign language or technical issues, and (c) a subset of documents from two custodians who were former employees, due to technical difficulties during collection. FDA's October 24th production contained documents from subsets (a) and (c). FDA's October 24th production also contained the foreign-language document from subset (b) and the technical-issue documents from subset (b) to the extent those technical issues were able to be corrected.

The following technical issues remain pending – some of which were identified following FDA's September 23 letter to the parties. FDA is working on resolving these issues as indicated:

- Approximately 40 stub files – FDA has requested that these files be restored from FDA's network, to the extent possible; afterwards, they will need to be re-loaded to the document review platform and then reviewed
- Approximately 1,114 partially-visible emails from custodian Alberto Gutierrez – there is no way to correct these email files. Accordingly, FDA is working to identify whether it has full versions of the emails from other custodians; to the extent it does not, it will produce the partially-visible emails
- An email container (.pst file) for custodian Katherine Serrano – FDA has requested that the files therein be restored from FDA's network; afterwards, they will need to be searched, loaded to the document review platform, and reviewed
- Approximately three documents with technical issues that have recently been corrected – FDA has reviewed and will produce.[3]

Additionally, FDA's collection, search, processing, and review for 14 additional custodians, requested by Defendants after the FDA's October 1st production, is ongoing.[4] FDA estimates that the documents from the 14 additional custodians will be loaded to the review platform by early December. Review time will depend on the volume of documents.

Finally, in response to the parties' meet and confer on October 23, 2019, FDA states as follows:

- Defendants' request for custodial documents from Agent for FDA's Office of Criminal Investigations ("OCI"): DOJ is handling production.

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[3] There exist approximately 10 documents with technical issues that cannot be fixed because the files are corrupt and 3 documents that are unreviewable because they require a connection to Theranos.com.

[4] FDA is also reviewing approximately 255 documents from custodian Alberto Gutierrez that recently came to the attention of undersigned counsel.

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- Defendants' request to confirm that document collection extended beyond email files, to include network files, hard copy files, and text messages: We have reached out to the custodians and/or FDA's information management personnel and will circle back to Defendants. To the extent additional documents are identified, FDA will process, review, and produce as soon as practicable.
- Defendants' request for confirmation that documents subject to a litigation hold, for employees who departed following the issuance of that hold, were preserved: FDA's information management personnel possesses, and has not deleted, all electronic documents for custodians who departed following the issuance of the litigation hold, mirroring what was in the custodians' possession at the time of departure. We are looking into the preservation of hard copy documents and will circle back with Defendants.
- Defendants' search string for category 1 documents: FDA confirms that there was a typo in the email to Defendants for that search string but not in the search string itself. The correct search string is: Theranos* AND (John.Carreyrou@dowjones.com OR dowjones.com OR WSJ OR "Wall Street Journal" OR "212-416-2309" OR "917-536-7824" OR Carreyrou)
- Defendants' concern with documents slipsheeted as "intentionally withheld": Documents slipsheeted as "intentionally withheld" are non-responsive, entirely privileged, or duplicative of other documents. We received a list from Defendant Balwani's counsel of particular "intentionally withheld"-slipsheeted documents that it wants FDA to re-produce in full. FDA will review the list and circle back with Defendants about these documents.
- Defendants' concern with the search terms utilized to identify documents potentially responsive to categories 2 and 4:
    - With respect to Defendants' contention that the search term "waiver" should have been included for category 2, a "CLIA Waiver" is unrelated to Theranos's CLIA compliance. CMS regulates compliance with the Clinical Laboratory Improvement Amendments ("CLIA") by conducting surveys of laboratories. CMS grants certificates of waiver for laboratories that only perform waived tests. FDA determines whether tests fall into the waived test category. Waived tests include simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. Laboratories that conduct only waived tests are not generally subject to routine CMS surveys, but may be subject to CMS surveys for cause. Laboratories must comply with CLIA whether an individual test has received a CLIA waiver or not. Accordingly, CLIA compliance is unrelated to a CLIA waiver. *See also* Dkt. #67, at 16-18 (Defendants explaining that category 2 is geared toward CMS's CLIA Surveys). The search string run by FDA for category 2 was: ((Theranos* AND ("Clinical Laboratory Improvement Amendments" OR CLIA) AND compl*) AND NOT Waiver) OR (Theranos* AND ("Clinical Laboratory Improvement Amendments" OR CLIA) and Survey)
    - With respect to Defendants' contention that "LDT" should have been included for category 4, FDA's search for category 4 is appropriately geared toward the types of FDA approval and/or clearance for devices such as

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those at issue in this case. The term "LDT" appears nowhere in the indictment or in Defendants' motion to compel. Defendants additionally contend that they should have received documents relating to laboratory developed tests ("LDTs") generally, whether or not they relate specifically to Theranos. That interpretation is inconsistent with the text of category 4 and finds no support in the arguments Defendants made in the motion to compel. The search string run by FDA for category 4 was: Theranos* AND (Clearance OR PMA OR "premarket approval" OR "De novo" or "Humanitarian Device Exemption" OR HDE OR "510(k)" OR "510k" OR "Investigational device exemption" or IDE OR "K152647" OR "K152965" OR "K152971" OR "Q151162" OR "Q151964" OR "Q160388" OR "Q160470" OR "K143236" OR "CW150009")

- Defendants' concern that there are purportedly fewer than expected documents for the year 2014: FDA searched for documents for the timeframe January 2010 through June 2018; that search was sufficient to capture documents in the year 2014.
- Defendants' concern with FDA's redactions for the law-enforcement privilege: FDA explained that it is possible that some such redactions were unrelated to Theranos. To the extent Defendants continue to have questions, they will provide a list of those documents to FDA. FDA will also voluntarily undertake a targeted re-review of those redactions.
- Defendants' concern with FDA's redactions for non-responsiveness and the deliberative process privilege: FDA explained that, for documents, or portions of documents, that were not responsive to the six motion to compel categories, it identified them as "non-responsive," which, in turn, was able to save the agency valuable review time that it otherwise would have had to spend to identify other applicable redactions to the non-responsive portions (such as, for example, third-party trade secret and confidential commercial information, which the agency is prohibited by law to produce absent a waiver from that third-party). As this material is non-responsive, there is no harm to Defendants. Additionally, FDA reiterated that it waived its deliberative process privilege with respect to Theranos-specific documents, but not as to non-Theranos-specific documents. The agency's deliberative process privilege redactions comply with the terms of the waiver.
- Defendants' request for a privilege log: FDA will circle back with Defendants regarding this request after the close of its review and production of documents.
- Defendants' request for additional metadata to accompany FDA's productions: FDA will provide the additional metadata for its October 9 production. Otherwise, FDA has already provided the additional metadata to the parties for its remaining non-manual productions.

FDA U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

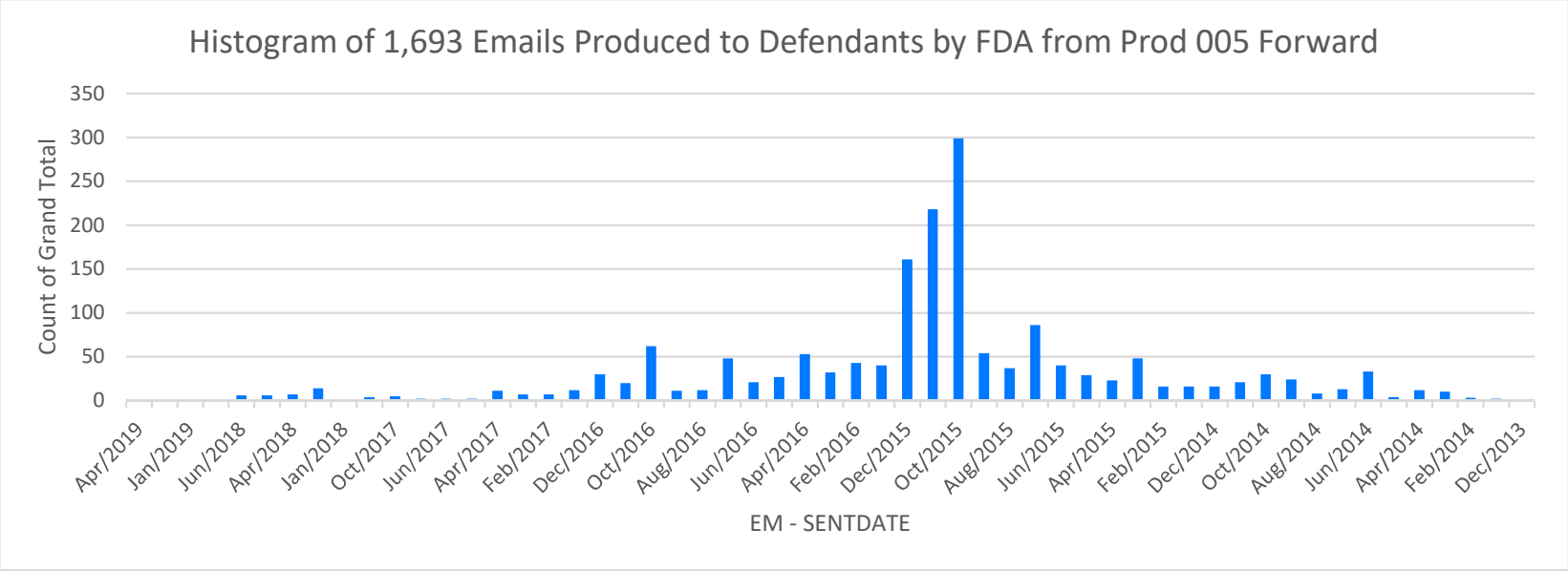
FDA continues to work diligently and in good faith to provide the parties with the documents responsive to the motion to compel.

Sincerely,

Marci B. Norton

Marci B. Norton
Senior Counsel

EXHIBIT B



EM - SENTDATE	Grand Total
Apr/2019	1
Feb/2019	1
Jan/2019	1
Jul/2018	1
Jun/2018	6
May/2018	6
Apr/2018	7
Mar/2018	14
Jan/2018	1
Nov/2017	4

Oct/2017	5
Aug/2017	2
Jun/2017	2
May/2017	2
Apr/2017	11
Mar/2017	7
Feb/2017	7
Jan/2017	12
Dec/2016	30
Nov/2016	20
Oct/2016	62
Sep/2016	11
Aug/2016	12
Jul/2016	48
Jun/2016	21
May/2016	27
Apr/2016	53
Mar/2016	32
Feb/2016	43
Jan/2016	40
Dec/2015	161
Nov/2015	218
Oct/2015	299
Sep/2015	54
Aug/2015	37
Jul/2015	86
Jun/2015	40
May/2015	29

Apr/2015	23
Mar/2015	48
Feb/2015	16
Jan/2015	16
Dec/2014	16
Nov/2014	21
Oct/2014	30
Sep/2014	24
Aug/2014	8
Jul/2014	13
Jun/2014	33
May/2014	4
Apr/2014	12
Mar/2014	10
Feb/2014	3
Jan/2014	2
Dec/2013	1
Grand Total	1,693

EXHIBIT C

Produced without Slip-Sheet/Redactions	6,858
Intentionally Withheld/Technical Issue Slip-Sheets	4,586
Redactions	944
Overall Total	12,388

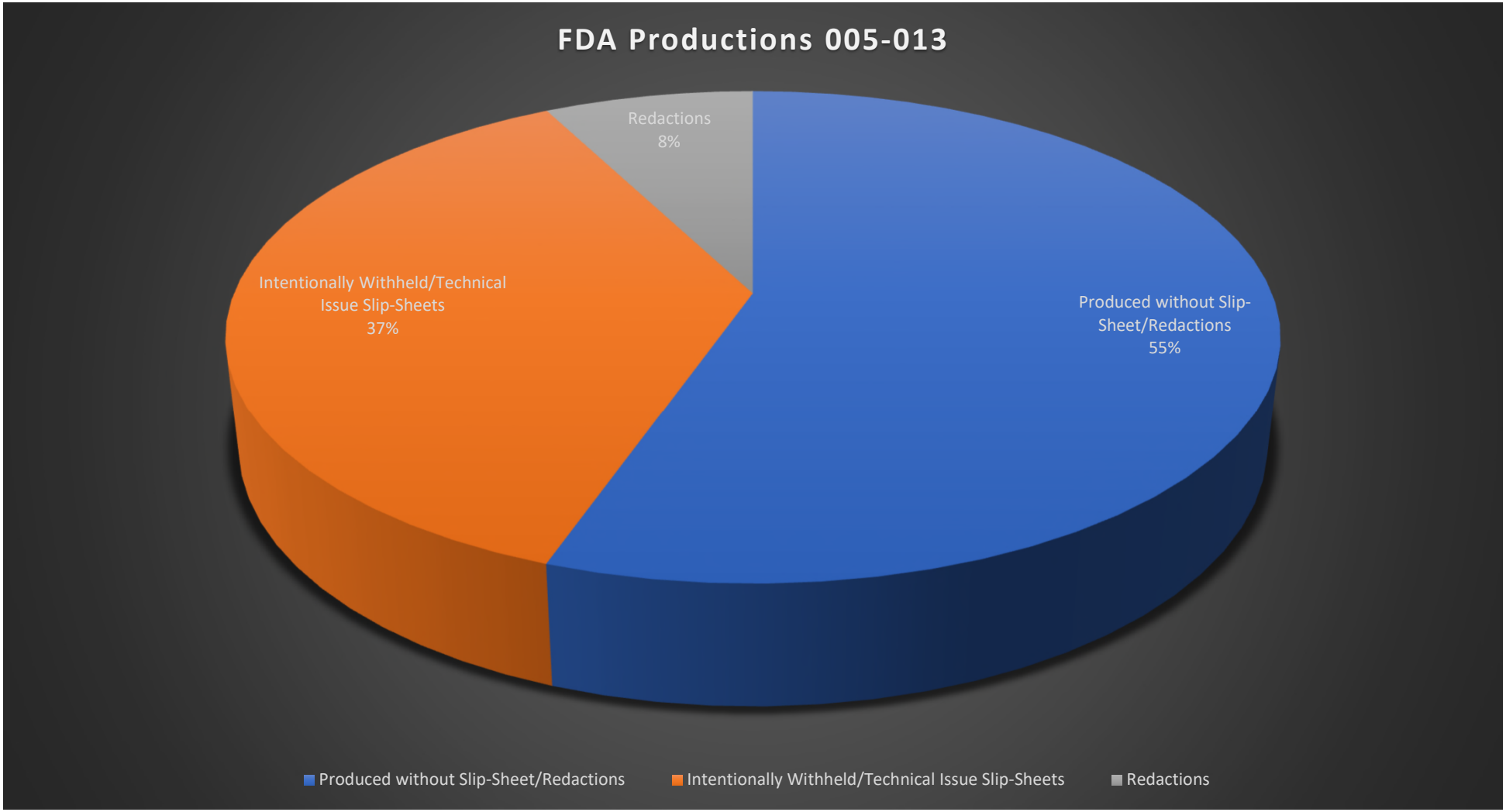


EXHIBIT D

From: Pilcher, Ian
To: CDRH-OIR-RegCounsel
Subject: Theranos inspection notebook
Date: Friday, June 02, 2017 11:25:00 AM
Attachments: Aug 16 2016 Theranos inspection notes.pdf
image001.png

Attached please see my inspection notes taken during the August 2016 inspection.

Thanks,

Ian

Ian Pilcher
Consumer Safety Officer
Division of Chemistry and Toxicology Devices
FDA/CDRH/OIR
301-796-6151

Intentionally Withheld

Intentionally Withheld

EXHIBIT E

Non-Responsive

Deliberative Process

Non-Responsive

Deliberative Process

Non-Responsive

Non-Responsive

Non-Responsive

Non-Responsive

From: Wiack, Michael
To: Lias, Courtney H; Kelm, Kellie; Grove, Andrew D
Cc: Gutierrez, Alberto; Hojvat, Sally A; Chan, Yung; Lovell, Stephen; Scherf, Uwe; El Mubarak, Haja Sittana
Subject: RE: Theranos TSPU & TLAS Procode and/or applicable regulation
Date: Thursday, November 20, 2014 3:26:05 PM

Deliberative Process

This is how they describe it:

These automated processes conducted by the TSPU are analogous to the preanalytic sample preparation performed by a
phlebotomist/lab technician in a service center, and include sample processing operations such as sample separation and addition of various reagents, as well as automated specimen acceptability and rejection processes (with multiple redundancies added in an automated manner). It is important to note that the automation of the preanalytic sample processing eliminates common human error in sample preparation and processing, a significant factor in laboratory test error rates.

The next operation performed by the TSPU is digital transmission of preanalytic specimen data to the Theranos CLIA-certified laboratory for analytic testing and post analytic processing. Again, this operation is analogous to a patient specimen collection site in which the collected and preanalytic processed sample would be physically transported to a CLIA certified laboratory for analytic and post analytic processing. However, in this case, rather than transporting the physical sample, the TSPU transmits data on the specimen to the Theranos CLIA laboratory for analytic testing and post-analytic processing via the TLAS.

Deliberative Process

Michael

From: Lias, Courtney H
Sent: Thursday, November 20, 2014 7:56 AM
To: Wiack, Michael; Kelm, Kellie; Grove, Andrew D
Cc: Gutierrez, Alberto; Hojvat, Sally A; Chan, Yung
Subject: RE: Theranos TSPU & TLAS

Thanks Michael –

Deliberative Process

Deliberative Process

Thanks,

Courtney

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
Food and Drug Administration
Ph 301-796-5458

From: Wiack, Michael
Sent: Wednesday, November 19, 2014 4:02 PM
To: Kelm, Kellie
Cc: Chan, Yung; Lias, Courtney H
Subject: RE: Theranos TSPU & TLAS

I asked Andy to add this to the agenda for next Mondays instrument/software meeting. I just want to be sure that all these issues are fully vetted office-wide.

From: Kelm, Kellie
Sent: Wednesday, November 19, 2014 11:53 AM
To: Wiack, Michael
Cc: Chan, Yung; Lias, Courtney H
Subject: RE: Theranos TSPU & TLAS

Michael,

I've cc'd Yung and Courtney. Deliberative Process

Deliberative Process

Kellie

Kellie B. Kelm, Ph.D
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration
10903 New Hampshire Avenue

WO66, Room 5648
Silver Spring, MD 20993-0002
phone - 301-796-6145
fax - 301-847-8513
kellie.kelm@fda.hhs.gov

From: Wiack, Michael
Sent: Wednesday, November 19, 2014 10:25 AM
To: Kelm, Kellie
Subject: Theranos TSPU & TLAS

Hi Kellie,

I know you were extensively involved in several Theranos Pre-subs. Do you remember if the issue of what product code/regulation(s) would cover the TSPU-TLAS?
We have a 510k in DMD for their HSV-1 assay and I'm reviewing the software.

Thanks

Michael Wiack
Scientific Reviewer
CDRH/OIR/DMD
301-796-6209

From: Pilcher, Ian
To: Gutierrez, Alberto; Lias, Courtney H
Subject: Law Enforcement
Date: Monday, January 25, 2016 4:46:31 PM

I just saw another WSJ article on Theranos, which Law Enforcement This article stated that CMS has found more issues at Theranos that are more serious than those found in their earlier inspections. Do we know about this CMS inspection and what they found? The article also makes some statements about whether or not the "Edison" systems were ever in use. Theranos has consistently told us that they were not in us. If there is anything that you think I should pass on to OCI about any of these, please let me know.

Thanks,

Ian

EXHIBIT F

PROPOSED PRETRIAL SCHEDULE

Date	Event
Monday, September 16, 2019	The Government previously agreed to complete its Rule 16(a) disclosures (except expert disclosures) by this date. The Government confirmed for the defense that it believes it complied with this production deadline. The defense believes the government has not satisfied its disclosure obligations. The Government shall remain obligated to produce any Rule 16(a) material it subsequently discovers.
Monday, December 16, 2019	All pretrial motions pursuant to Rule 12(b)(3)(A)-(D) are to be filed.
Monday, January 13, 2020	Responses to Rule 12(b)(3)(A)-(D) motions due.
Monday, January 27, 2020	Replies in support of Rule 12(b)(3)(A)-(D) motions due.
Monday, February 3, 2020	The Government shall complete its disclosure of *Jencks* materials. The Government shall remain obligated to produce any *Jencks* materials it subsequently discovers.
Monday, February 10, 2020	Hearing on Rule 12(b)(3)(A)-(D) motions.
Friday, March 6, 2020	The Government shall serve a summary under Rule 16 for each expert witness that it intends to call at trial in its case-in-chief.
Friday, March 6, 2020	The Government shall provide notice of any evidence of other crimes, wrongs or acts which the Government intends to offer under Federal Rule of Evidence 404(b).
Wednesday, April 29, 2020	Each defendant shall serve a summary pursuant to Rule 16 for each expert witness that defendant intends to call at trial in the defendant's case-in-chief.
Friday, May 1, 2020	Each defendant shall complete the defendant's Rule 16 disclosures other than expert disclosures.
Friday, May 1, 2020	The Government shall serve witness and exhibit lists for its case-in-chief. The Government shall identify any statement the Government intends to offer under Federal Rule of Evidence 801(d)(2)(E).

Wednesday, May 13, 2020	The Government shall serve a summary pursuant to Rule 16 for each expert witness that it intends to call at trial in rebuttal to expert testimony offered by any defendant.
Friday, May 15, 2020	Each defendant shall serve witness and exhibit lists for the defendant's case-in-chief.
Friday, May 22, 2020	Motions *in limine* and motions relating to experts due.
Friday, May 22, 2020	Proposed jury instructions, juror questionnaire, and voir dire questions due.
Monday, June 8, 2020	Responses to motions *in limine* and motions relating to experts due.
Monday, June 8, 2020	The parties shall file a pretrial conference statement addressing the matters set forth in Local Rule 17.1-1. The Government shall advise the Court that it has produced all *Brady* and *Giglio* information in its possession and will continue to produce any the government subsequently discovers.
Monday, June 22, 2020	Replies in support of motions *in limine* and motions relating to experts due.
Thursday, July 9, 2020	Pretrial Conference
Tuesday, July 28, 2020	Jury Selection
Tuesday, August 4, 2020	First Day of Trial